Appendix G - 510(k) Summary for the Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)

K091323

I. General Information

Submitter: INTERmedic Arfran, S.A.
Avda. Josep Tarradellas, 91
08029 Barcelona
SPAIN

Contact Person: Francesc Sota
Technical Director,
INTERmedic Arfran, S.A.

Summary Preparation Date: June 2, 2009

II. Names

Device Names: Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)

Primary Classification Names: Laser Powered Surgical Instruments (and accessories)

III. Predicate Devices

- INTERmedic Arfran, S.A. - INTERmedic Diode Laser Diode Family (K053540)
- Biolitec, Inc. - 180W Ceralas D 980nm Diode Laser (Model D180) (K083682)

IV. Product Description

The modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180), and the delivery accessories that are used with it, is comprised of the following main components:

- Laser console with fiber port and RF ID bracket
  - Operating software
- Detachable footswitch
- Delivery device accessories (fiber optic, handpieces and scanner)

V. Indications for Use

The modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180) is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialties including: Urology, Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/Neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.

The Indications for Use of the modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180) are provided in **Appendix D**.

VI. Rationale for Substantial Equivalence

The modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180) shares the same indications for use, device operation, technical and functional capabilities, and therefore is substantially equivalent to the predicate INTERmedic Diode Laser Family (K053540) and shares similar functional capabilities as the predicate Biolitec 180W Ceralas D 980nm Diode Laser (Model D180) (K083682).

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180) is substantially equivalent to the predicate INTERmedic Diode Laser Family (K053540) and the predicate Biolitec 180W Ceralas D 980nm Diode Laser (Model D180) (K083682).

VIII. Conclusion

The modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180) was found to be substantially equivalent to the predicate devices.

The modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180) shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

INTERmedic Afran S.A.
% A.L. Voss Associates
Ms. Anne Worden
3637 Bernal Avenue
Pleasanton, California 94566

JUN - 4 2009

Re: K091323
Trade/Device Name: The Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 1, 2009
Received: May 5, 2009

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K091323**

Device Name: **The Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)**

Indications for Use:

The Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180) is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialties including: Urology, Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/Neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.

Examples include:

Laser 980 nm
Urology:
- Lesions of external genitalia
- Circumcision
- Condyloma
- Bladder tumors
- Bladder neck incisions
- Vaporization of the prostate.

*** 6 pages total ***

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091323

510(k) Number (if known): **K091323**

Device Name: **The Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)**

Indications for Use: Continued

Laser 980 nm

General Surgery:

- Rectal and anal hemorrhoidectomy
- Mastectomy
- Dermabrasion
- Appendectomy (open and laparoscopic)
- Bowel resection (open and laparoscopic)
- Colectomy
- Liver resection
- Resections of organs
- Thyriodectomy
- Adhesiolysis
- Hepatobiliary tumors
- Throacotomy
- Cholecystectomy (open and laparoscopic)
- Condyloma
- Breast biopsy

Neurosurgery:

- Percutaneous Disc Decompression
- Discectomy
- Hemostasis in conjunction with meningiomas

*** 6 pages total ***

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

Page 2 of 6

510(k) Number K091322

510(k) Number (if known): K091323

Device Name: **The Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)**

Indications for Use: Continued

Laser 980 nm

Gynecology:
- Cervical conization
- Myomectomy
- Endometrial ablation
- Ovarian cystectomy
- Appendectomy

Ophthalmology:
- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor excision
- Blepharoplasty

Orthopedics:
- Dissect and coagulate

Gastroenterology:
- Hemostasis of colonoscopy
- Hemostasis of esophageal varicies
- Excision of polyps

Arthroscopy:
- Chondromalacia
- Synovectomy
- Menisectomy

*** 6 pages total ***

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091323

510(k) Number (if known): K091323

Device Name: **The Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)**

Indications for Use: Continued

Laser 980 nm

Thoracic Surgery:
- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

Pulmonology:
- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary obstruction

Otolaryngology ENT:
- Removal of benign lesions from the ear, nose and throat
- Excision of carcinoma of the larynx
- Incision and excision of carcinoma in situ
- Neck dissection
- Laryngeal papillomectomy
- Removal of vocal cord/fold nodules, polyps and cysts

*** 6 pages total ***

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091323

510(k) Number (if known): K091323

Device Name: **The Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)**

Indications for Use: Continued

Laser 980 nm

Dental Applications:

- Frenectomy
- Frenotomy
- Biopsy
- Pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening

Pulmonary Surgery:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary or stricture

Cardiac Surgery:

- Coagulation and hemostasis of cardiac tissue

Dermatology/ Aesthetics:

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasis, veinulectasisas of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyogenic granuloma, lymphangioma and lymphagiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venus lakes, Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.

*** 6 pages total ***

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091323

510(k) Number (if known): K091323

Device Name: **The Modified INTERmedic Diode Laser 980nm System (MULTIDIODE SST 180)**

Indications for Use: Continued

Laser 980 nm

Dermatology/ Aesthetics: Continued

- Dermatological surgery: Chondyloma acuminate, warts, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcoma. Warty leucoplasy and ulcers debridement.
- Seborrheic keratoses
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin types 1-V

Plastic Surgery:
- Cut, coagulation & vaporization
- Resurfacing
- Blepharoplasty

Vascular Surgery:
- Endoluminal or endovenous laser surgery for saphenous incompetent veins

*** 6 pages total ***

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091323